

Remarks

Claims 13-23 are pending in the application.

Claims 13 and 19 have been amended to cancel non-elected material.

Claim 13, 19-22 has been amended by cancelling "derivative" and adding "salt, solvate or N-oxide". Support for this amendment may be found on page 5, line 36 and page 6, lines 11-15.

Claim 20 has been amended as indicated and support for this amendment can be found on page 11 lines 18-20. Claim 20 has been amended to add the definition "M is an alkali metal". Support for this amendment can be found on page 8 line 15.

Priority

Applicants enclose Form PCT/DO/EO/905 that indicates the priority document was submitted in parent application number 09/807,275.

Claim Rejection – 35 U.S.C. §112 second paragraph

Claims 13-22 are rejected for alleged indefiniteness under 35 U.S.C. 112 second paragraph.

The pending Office Action alleges that the term "derivative" in claims 13, 19-22 is open-ended and therefore indefinite. In order to expedite prosecution while reserving the right to reintroduce cancelled subject matter, Applicants have cancelled the term "derivative" and added "pharmaceutically acceptable salts, solvates or N-oxides thereof". Support for this amendment can be found on page 5, line 36 and page 6, lines 11-15.

The definition of "most preferably methoxy" has been cancelled from claim 15 and reintroduced as the subject matter in now dependent claim 23.

The definition of "M is an alkali metal" has been added to claim 20 and finds support in the specification on page 8 line 15.

In accordance with the Examiner's suggestion, R^{11'} has been changed to R¹¹ in claim 20.

Claim 20 has been amended to cancel reference to the description "groups convertible thereto" and added "wherein R^{1'}, R^{2'}, R^{3'} and R^{4'} are R¹, R², R³ and R⁴ optionally containing hydroxyl protecting groups, or R^{3'} is a carboxy ester containing group, or R^{4'} is H or a protecting group, R^{11'} is R¹¹". Support for this amendment can be found on page 11 line 18-20 of the specification.

The Examiner has alleged that "the metes and bounds of the conversion of one substituent to other substituents is unclear in view of the large number of diverse substituents in each variable....". Applicants wish to traverse this rejection by highlighting the detailed description of interconversions of A-B, R¹⁻⁴ and R¹¹ which can be found from page 10 line 19 to page 12 line 29. Furthermore, Applicants contend that one of skill in the art readily appreciates the significant number of ways to proceed from one of the listed substituents to another. Accordingly, the teaching of the specification further coupled with the knowledge of one of skill in the art, readily leads one to an appreciation of the scope of the claimed methods which includes the interconversion of one or more substituents to one or more different substituents.

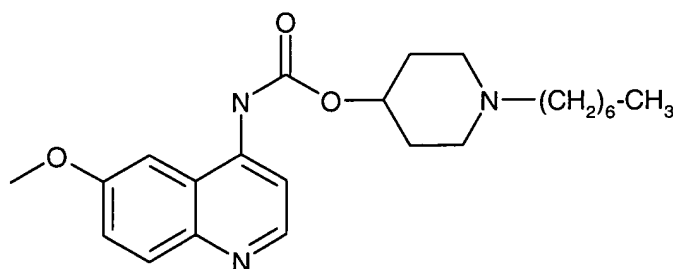
Claim Rejections for Provisional Rejection for Obviousness-Type Double Patenting

Claims 13-17, and 20-22 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending applications 10/477900, 10/484563, and US Patent No. 6602882. Applicants wish to address these rejections for the reasons set forth in detail below.

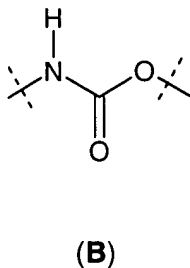
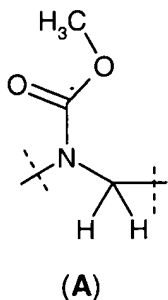
Application Number 10/477900 – Applicants note that the instant application is cited for alleged obviousness-type double patenting against copending 10/477900. Without arguing the rejection on its merits at this point, Applicants simply wish to point out that Application Number 10/477900 has a provisional filing date of May 25, 2001 which is subsequent to the international publication date (April 20, 2000) of the instant application. Accordingly, Applicants believe that an obviousness-type double patenting rejection might not be a proper rejection to make in this application, and will leave the matter here for the Examiner's further consideration.

Application 10/484563 - Applicants note that the instant application is cited for alleged obviousness-type double patenting against copending 10/484563. Without arguing the rejection on its merits at this point, Applicants simply wish to point out that Application Number 10/484563 has a provisional filing date of (May 25, 2001), which is subsequent to the international publication date (April 20, 2000) of the instant application. Accordingly, Applicants believe that an obviousness-type double patenting rejection might not be a proper rejection to make in this application and will leave the matter here for the Examiner's further consideration.

Patent No. 6602882 - The instant Office Action alleges that the instant pending application is unpatentable over claims in US Patent 6602882. The Office Action alleges that although the conflicting claims are not identical, they are not patentably distinct from each other. Applicants wish to traverse the Office Action and begin by pointing out that contrary to the Examiner's assertions, Applicants believe there is no overlap between the compounds exemplified in US Patent 6602882 and the claimed genus of the pending application. In particular, Applicants note that the compound 1-heptyl-4-[N-6-methoxyquinoline-4-yl]-aminocarbonyloxy]-piperidine of claim 7 of US Patent 6602882 contains a carbamate linker connecting the 4-position of the quinoline ring with the 4-position of the piperidine ring present in that compound (see below):



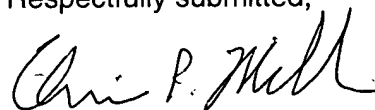
In contrast, Applicants can find no description of the correlate "aminocarbonyloxy" linker in the pending case. In particular, the pending application defines a group $A-B-(CH_2)_n$ (where n is 0, 1, or 2). The Examiner has suggested that A can be NR^{11} and B can be CR^8R^9 , where R^8 and R^9 can be hydrogen, and $n = 0$, thus rendering the possibility of the linker: $N(R^{11})-CH_2-$. This does not define a carbamate (or urea) linker as specified in US Patent 6602882. If R^{11} were specified as methoxycarbonyl as the Examiner further suggests, $-N(R^{11})-CH_2-$ becomes: $N(CO_2Me)-CH_2-$ (**A**, as shown below) which does not overlap at all with the $NH-C(=O)-O-$ (**B**, as shown below) of US Patent 6602882. The structures of the two groups (**A** and **B**) connecting the quinoline (or naphthyridine ring) to the 4-position of the piperidine ring are illustrated below:



Applicants can find no teaching or suggestion which would motivate one to substitute **B** as disclosed in US Patent 6602882 for **A** as defined above.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the subject application is in condition for allowance. If the Examiner has any remaining objections or concerns, the Examiner is respectfully requested to contact Applicants' undersigned attorney to resolve such issues and advance the case to issue.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Chris P. Miller". The signature is fluid and cursive, with the first name "Chris" and last name "Miller" clearly distinguishable.

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| 11 OCT 99 | | 14 OCT 98 |

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DATE MAILED: 07 JUN 2001

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

- The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☒ an Elected Office (37 CFR 1.495):
 - ☒ U.S. Basic National Fee.
 - ☐ Copy of the international application.
 - ☐ Oath or Declaration of inventors(s).
 - ☐ Copy of Article 19 amendments.
 - ☒ Priority Document.
 - ☒ The International Preliminary Examination Report in English and its Annexes, if any.
 - ☒ Translation of Annexes to the International Preliminary Examination Report into English.
 - ☐ Indication of Small Entity Status.
 - ☐ Translation of the international application into English.
 - ☐ Translation of Article 19 amendments into English.
 - ☐ Other:
- ☒ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.
 - ☐ U.S. Basic National Fee.
 - ☐ Copy of the international application.
- The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:
 - ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
 - ☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
 - ☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
 - ☒ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.
 - ☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
 - ☒ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).
- Additional claim fees of \$_____ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.
- ☐ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

- If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.
- ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

A copy of this notice MUST be returned with this response.

- Enclosed: ☐ PCT/DO/EO/917 ☐ Notice of Defective Translation
☐ PTO-875 ☐ PCT/DO/EO/920

Pat Booker, Paralegal

FORM PCT/DO/EO/905 (March 2001)

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